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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/069,598 | 02/28/2002 | Shinji Shimizu | 2109-24 | 3579 |
| 23117 | 7590 | 12/13/2004 | EXAMINER | |
| NIXON & VANDERHYE, PC 1100 N GLEBE ROAD 8TH FLOOR ARLINGTON, VA 22201-4714 | | | LE, EMILY M | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1648 | |

DATE MAILED: 12/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/069,598

Applicant(s)

SHIMIZU ET AL.

Examiner

Emily Le

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 2/28/01, 05/30/02 and 10/14/04.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) 1-7 and 19-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8-18 is/are rejected.
- 7) ☒ Claim(s) 8-18 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 2/28/02.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group III in the reply filed on 10/14/2004 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Status of Claims

2. Claims 1-26 are pending. Claims 1-7 and 19-26 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 10/14/2004. Claims 8-18 are currently under examination.

Specification

3. The disclosure is objected to because of the following informalities: the use of trademarks. The use of trademarks has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Appropriate correction is required.

Claim Objections

4. Claims 8-18 are objected to because of the following informalities: the inclusion of a comma between "complication factor" and "comprising" is unnecessary.
5. Claim 9 is objected to because of the following informalities: the claim recites two periods, "...".
6. Claim 12 is objected to because of the following informalities: the claim recites "the a". An amendment to the claim to recite "the" or "a" would overcome this objection. Appropriate correction is required.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 8-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 8 is rendered indefinite because of "the antibody", "at least one", and "claim 1". Directing at the limitation "the antibody", this limitation lacks proper antecedent basis. Claim 8 does not recite of an antibody, thus, the limitation "the antibody" lacks proper antecedent basis. Moreover, in the instant, it is unclear what kind of antibody is encompassed by the limitation "the antibody".

Regarding the limitation, "at least one", it is unclear if the ligand of the claimed invention is capable of binding to both categories of substances recited within the claim,

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a substance capable of binding to a peptide and a substance capable of binding to an antibody; OR if the ligand of the claimed invention is capable of binding to a substance selected from the group consisting of a substance that is capable of binding to a peptide and a substance capable of binding to an antibody, in the alternative.

Lastly, regarding the limitation "claim 1", it is unclear what is encompassed by the recitation "claim 1". Claim 1 has been withdrawn from examination for being directed to a non-elected invention. Ergo, it is not clear what is intended by the limitation "claim 1".

Additionally, it is not clear if the "-" notation recited in claim 14 is directed at chemical, physical bonds or both. The specification notes that the bond shared between the ligand and the carrier can be chemical or physical. In the instant, the use of "-" are typically noted as chemical bonds; however, because of the disclosure, as noted, it is not clear if such bonds are physical, chemical bonds, or both types of bonds. Clarification is necessary to determine the metes and bounds of formula [I].

9. Claim 9 recites the limitation "the material" in line 2. There is insufficient antecedent basis for this limitation in the claim.

10. Claim 12 recites the limitation "the functional group" in line 2. There is insufficient antecedent basis for this limitation in the claim.

11. Claim 14 is also indefinite. It is unclear what is encompassed by the formula designated as formula [I]. Currently, as written, formula [I], it is unclear if Y or Z is the ligand. Additionally, it is unclear what is intended by the limitation "a functional group of an amide or a ketone". In the instant, amides and ketones are functional groups. It is not

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clear what is encompassed by a functional group of a functional group. The same is also true for "a functional group having at least one carbon atom".

12. Claim 15 recites the limitation "at least one of an amino group or hydroxyl group" in lines 2-3. There is insufficient antecedent basis for this limitation in the claim. None of the previous claims indicates that an amino group or a hydroxyl group is present in the water-insoluble carrier.

13. Claims 15-18 recite the limitation "compound [I]" in line 2. There is insufficient antecedent basis for this limitation in the claim. It is noted that there exist proper antecedent basis for formula [I], but not for compound [I].

14. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

15. Claims 14-18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In the instant, claims 14-18 are drawn to an adsorbent that comprises a water-insoluble carrier immobilized ligand thereto that follow a particular disclosed formula, set forth as formula [I]:

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(Water-insoluble Carrier)-(Y)_a-Z [I]

Y: a functional group of an amide or a ketone

Z: -(cyclic compound 1)_l-(open-chain compound)_m-(cyclic compound 2)_n-NH₂ and is a functional group having at least one carbon atom

a, l, m, and n: 0 or an integer of equal to or more than 1

Formula [I] does not define a chemical compound. Formula [I] defines the components that must be present in the claimed composition. In the instant, the minimum component that must be present is a water-insoluble carrier and NH₂. While the claims do clearly define the minimum component that must be present; it remains unclear of what else should or should not be present in formula [I]. Additionally, it remains unclear if the two components that are required at a minimum are bonded physically, chemically, or both. The limitations that are provided for Y and Z encompass an enormously abundant number of chemical compounds. Y and Z are directed to an extreme multitude of chemical compounds. Applicant has only demonstrated a limited number of species that follows the limitations that is recited within formula [I]. Thus, Applicant has adequate written description for such compositions. However, to the contrary, Applicant does not have adequate written description of the multitude of compounds that is encompassed by formula [I]. The skilled artisan cannot conceive all chemical compounds that are encompassed by formula [I].

To provide adequate written description and evidence of possession of a claimed genus, which is all compounds that fits the description set forth in formula [I], the

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specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factors present in the claims is a generic formula, formula [I], which encompasses a extreme multitude of chemical compounds, and a generic requirement of the ligand being capable of binding to at least a substance that binds to a peptide and/or an antibody, any peptide and any antibody. There is not even identification of any particular portion of the structure that must be conserved, which part of formula [I] is the ligand, or the category/type of substance the ligand binds. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the ‘written description’ inquiry, *whatever is now claimed*.” (See page 1117.) The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.” (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of water-insoluble immobilized ligand thereto, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of making compounds that fits the requirement

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set forth in formula [I]. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of making it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class.

Therefore, only compounds that is disclosed in the specification, which meets the requirement of formula [I], but not the full breadth of the claims meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Claim Rejections - 35 USC § 102

16. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

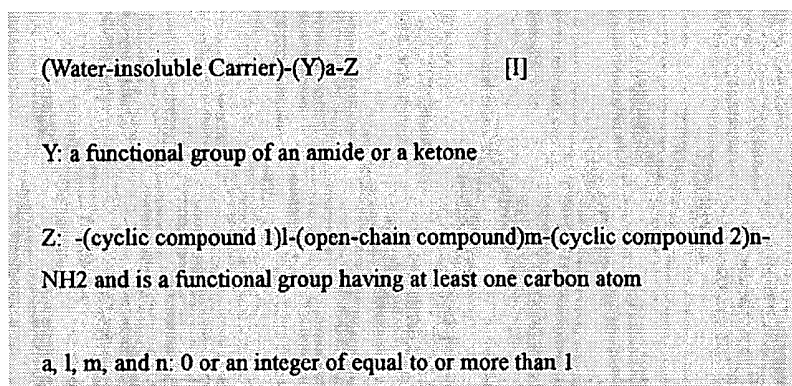
17. Claims 8-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Cerami et al. (U.S. Patent No. 5850840).

The claims are directed to an adsorbent for a diabetic complication factor. The adsorbent comprises a water insoluble carrier immobilized a ligand thereto, wherein the ligand being capable of binding to at least one of a substance capable of binding to a

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peptide and/or a substance capable of binding to an antibody. The claims require the adsorbent be used in extracorporeal circulation. The claims later specifies that the ligand be a non-bioorganic molecule and comprises a cationized atom or a reactive amine, wherein the cationized atom is later specified as a nitrogen. The claims also require that the functional group containing the cationized nitrogen be derivable from at least one selected from the group consisting of acyclic or cyclic aliphatic compounds, aromatic compounds and heterocyclic compounds. The claims also require that the water-insoluble carrier immobilized ligand thereto to follow the following formula,

formula



[I]:

The claims also require that the functional group Y in the above formula to be bound to at least one of an amino group or a hydroxyl group of the water-insoluble carrier; the open-chain compound in formula [I] be a hydrocarbon; cyclic compound 1 and 2 in formula [I] be an aromatic or a heterocyclic compound.

Cerami et al. teaches an adsorbent comprising a water insoluble carrier (cellulose fibers) immobilized a ligand thereto, wherein the ligand being capable of binding to at least one of a substance capable of binding to a peptide and/or a

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substance capable of binding to an antibody. The ligand of Cerami et al. is a non-bioorganic molecule and comprises a cationized atom, a reactive amine, wherein the cationized atom is nitrogen. The functional group containing the cationized nitrogen is derivable from at least one selected from the group consisting of acyclic or cyclic aliphatic compounds, aromatic compounds and heterocyclic compounds. Furthermore, since the adsorbent of Cerami et al. is water-insoluble with a non-bioorganic ligand immobilized thereto, the adsorbent of Cerami et al. can be used in extracorporeal circulation. Thus, Cerami et al. teaches the claimed adsorbent, including those fitting the requirements of formula [I]. Cerami et al. anticipates the claimed invention.

18. Claims 8-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Anspach et al. (J. Chromatogr. 1990 Jan 19; 499: abstract.).

Anspach et al. teaches of an adsorbent comprising a water insoluble carrier (cellulose) immobilized a ligand thereto (reactive amine), wherein the ligand being capable of binding to at least one of a substance capable of binding to a peptide and/or a substance capable of binding to an antibody. The ligand of Anspach et al. is a non-bioorganic molecule and comprises a cationized atom, a reactive amine, wherein the cationized atom is nitrogen. The functional group containing the cationized nitrogen is derivable from at least one selected from the group consisting of acyclic or cyclic aliphatic compounds, aromatic compounds and heterocyclic compounds. Furthermore, since the adsorbent of Anspach et al. is water-insoluble with a non-bioorganic ligand immobilized thereto, the adsorbent of Anspach et al. can be used in extracorporeal circulation. Thus, Anspach et al. teaches the claimed adsorbent, including those fitting

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the requirements of formula [I]. The teaching of Anspach et al. is further evidenced by Applicant's admission, see lines 5-7, page 26 of the disclosure. Ergo, Anspach et al. anticipates the claimed invention.

Conclusion

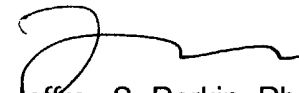
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Le whose telephone number is (571) 272 0903. The examiner can normally be reached on Monday - Friday, 8 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



E. Le



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